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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/661,948 | 09/12/2003 | Eli D. Ehrenpreis | 27373/38613A | 8386 |
| 4743 | 7590 | 01/09/2007 | EXAMINER | |
| MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | HA, JULIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 31 DAYS | 01/09/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/661,948 | EHRENPREIS, ELI D. |
| | Examiner | Art Unit |
| | Julie Ha | 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on September 20, 2006 is acknowledged. The Applicant elected with traverse the claims of Group I (claims 1-12), methods of monitoring gastric emptying, diagnosing a gastric emptying disorder and diagnosing gastroparesis in an animal, is acknowledged. In previewing, it was determined that the Restriction was insufficient since it did not contain an Election of species for wherein an agent is a sugar and a list of compounds disclosed. Thus, the previous Restriction has been vacated and a new Restriction follows below. Restriction between the Groups is same except the Restriction now contains an Election of species. Claims 1-40 are pending in this application.

Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, drawn to methods of monitoring gastric emptying, diagnosing a gastric emptying disorder and diagnosing gastroparesis in a mammal, classified in class 436, subclasses 50, 811.
 - II. Claims 13-17, drawn to a method of screening for a compound that modulates gastrointestinal motility in a mammal, classified in class 436, subclass 815.
 - III. Claims 18-40, drawn to formulations comprising D-xylose and a kit comprising a marker agent, classified in various subclasses of class 514, depending on the marker contemplated and class 514, subclass 23.

The inventions are distinct, each from the other, for the following reasons:

2. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different effects. The D-Xylose absorption test is a relatively specific measurement of proximal small-bowel absorption.

The Groups have acquired a separate status in the art as shown by their different classification and their recognized, divergent subject matter. The searches required for each Group are not co-extensive resulting in an undue burden to the Examiner. Each Group is capable of supporting a separate patent. Thus restriction for examination purposes as indicated is proper.

Further, claims 27-40 are generic to the following disclosed patentably distinct species: first and second marker agents. The species are independent or distinct because a prior art reference anticipating claim 27 with respect to one species that is a first or second marker would not render the claim obvious under 35 U.S.C. 103 with respect to another species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 80g.02(a).

Applicant is advised that to be complete, the reply to this requirement must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Where the Examiner has required restriction between product and process claims and Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after Final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. Until an elected product claim is

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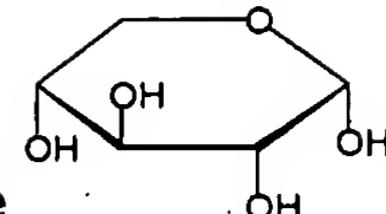
found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)*," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Election

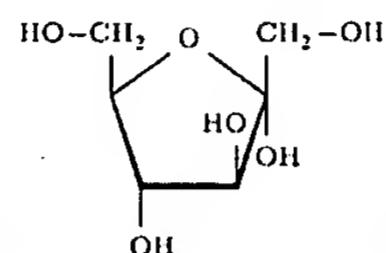
3. This application contains claims directed to the following patentably distinct species: D-xylose, D-galactose, D-mannose, D-fructose, L-fucose, L-rhamnose, and L-sorbose; acetaminophen, aspirin, caffeine, cephalosporins, beta-lactam antibiotics, cimetidine, ranitidine, famotidine, nizadidine, alprazolam, gentamicin, amikacin, vancomycin, diclofenac, ibuprofen, D-amino acids, beta carotene, ascorbic acid, sulfur dioxide, biotin, inositol, zinc, vitamin B12, folate, aluminum sulfate, eugenol, citral, vanillin, and malic acid. The species are independent or distinct because the sugars listed above are patentably distinct due to their different structures. For example D-

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xylose and D-fructose are structurally distinct since D-xylose



has the



chemical formula $C_5H_{10}O_5$ and D-fructose

has the chemical formula

$C_6H_{12}O_6$. Search for one would not lead to the other. The species of agents listed are independent and distinct because the agents are all patentably structurally distinct. For example, acetaminophen has the chemical formula $C_8H_9NO_2$ while caffeine has the chemical formula $C_8H_{10}N_4O_2$. Search for one would not necessarily lead to the other. Similarly, zinc is a transition metal and D-amino acids are amino acids that make up the peptide/proteins. Search for zinc would not lead to amino acids.

The search for each of the inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the election of species for examination purposes as indicated above is deemed proper.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5 and 6 are generic.

For Group I (claims 1-12), the examiner on record respectfully requests the Applicant to elect a single disclosed species from claims 5 and 6. For example, elect a single disclosed sugar from claim 5 and elect a single disclosed agent from claim 6.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

4. A telephone call was made to Nabeela MeMillian/Jeanne Brashear on December 14, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

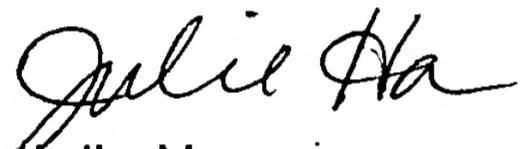
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Julie Ha
Patent Examiner



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PRIMARY EXAMINER